DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 23, 2016

Candela Corporation
% Ms. Janice M. Hogan
Hogan Lovells US LLP
1835 Market St., 29th Floor
Philadelphia, Pennsylvania, 19103

Re: K142372
Trade/Device Name: PicoWay Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 26, 2014
Received: August 26, 2014

Dear Ms. Hogan:

This letter corrects our substantially equivalent letter of October 30, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142372

Device Name
PicoWay Laser System

Indications for Use *(Describe)*
The PicoWay Laser System is indicated for the following at the specified wavelength:

532nm:
Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow, and orange.

1064nm:
Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue, and purple.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
PicoWay Laser System (K142372)

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Ruthie Amir Global Vice President of Clinical and Regulatory Affairs Tel: 508-358-7400 x330 Fax: 508-358-5602
Date prepared:	March 30, 2016
Trade Name:	PicoWay Laser System
Common Name:	Dermatology Laser System
Classification:	Class II Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810) Product Code GEX
Predicate Devices:	Cynosure PicoSure™ workstation (K121346) (Primary Predicate) Medlite C6 Q-Switched Nd:YAG Laser (K014234) These predicates have not been subject to a design-related recall.

Intended Use / Indications for Use:

The PicoWay Laser System is indicated for the following at the specified wavelength:

532nm
Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.

1064nm
Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.

Description:

The PicoWay Laser System is a solid state laser capable of delivering energy at wavelengths of 1064 nm or 532 nm at short durations of 240-750 picoseconds (ps) at repetition rates up to 5 Hz. The device system is comprised of a system console, an articulated arm, and an attached

handpiece. The laser output at each wavelength is generated within the laser chassis and delivered to the skin through an articulated arm delivery system terminated by a zoom handpiece (HP). The light-weight and ergonomic zoom handpiece allows the spot size on the skin to be easily adjusted from 3 mm to 6 mm in steps of 1 mm. The system includes an internal calibration port with an internal meter located on the control panel of the system console, which is used to verify the transmission of the laser beam into the articulated arm. The PicoWay system control panel enables the user to select the desired energy density (fluence) level and repetition rate. The control panel is also used to obtain feedback from the system, such as the number of pulses delivered or spot size selected.

Technological Characteristics:

The PicoWay Laser System has the same intended use and similar indications for use, technological characteristics, and operating principles as the Cynosure PicoSure™ workstation (K121346) and the Medlite C6 Q-Switched Nd:YAG Laser (K014234). The PicoWay device design and components are very similar to those of the predicate devices. For each of these device systems, the treatment handpiece is attached to an articulating arm that is connected to the main system console. For each system, the user interface is located at the front/top of the console. For the PicoWay and predicate devices, the laser output at each wavelength is generated within the laser chassis and delivered to the skin through an articulated arm delivery system with a handpiece attached to the end. The handpiece allows the spot size on the skin to be adjusted according to device specifications. Each system thus consists of the articulating arm (and attached handpiece), as well as an electrically powered system console that houses the software, user interface, and produces the laser energy. All three of the devices include an aiming beam feature that assists the user in delivering the treatment beams, but does not deliver any therapeutic energy. The PicoWay provides similar key design aspects, including similar spot sizes, laser wavelengths, pulse width, and laser types, as its predicate devices. The frequency (repetition rate) of the PicoWay System is within the frequency range of the predicates. Further, each of the devices presents a range of spot sizes to allow the user to choose the most appropriate spot size for each patient. Differences in the specific maximum energy levels and fluence delivered with the PicoWay and the predicate devices do not raise any new types of safety or effectiveness questions because the PicoWay parameters are within the range of maximums of the predicate devices. Further, PicoWay performance and safety were evaluated and demonstrated in the clinical study.

Performance Data:

Electrical safety and electromagnetic compatibility (EMC) testing for the PicoWay Laser System was conducted by an independent test laboratory in accordance with IEC 60601-1, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance. The PicoWay System was determined to be in conformance with applicable IEC standards (IEC 62366, 60601-1, 60601-1-6, IEC 60601-2-22, and IEC 60825-1).

The biocompatibility of the PicoWay device is also based on the established biocompatibility of previously cleared devices, and on biocompatibility evaluations consistent with the guidelines in

FDA's "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'" Guidance Document.

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Device software verification and validation results demonstrated that testing results were found acceptable for software release.

All performance testing demonstrated that the PicoWay Laser System performs according to specifications and functions as intended.

Clinical Data:

A single arm, prospective, self-controlled multicenter study was conducted to evaluate the safety and effectiveness of the PicoWay System. The clinical evaluation of 60 subjects (75 tattoos) at 3 investigational sites in the U.S. demonstrated that the PicoWay performs as intended and presents a favorable safety profile for its indicated use. The majority of subjects were female, Caucasian, with a mean age of 34 years.

Each subject was assessed at baseline, post-treatment, and during follow up after final treatment. The tattoos were photographed before treatment, immediately after treatment, as well as during follow up visits after treatment end. For the primary endpoint analysis, the subjects' tattoos were evaluated by three blinded independent evaluators. In addition, investigator and subject assessments were also captured as part of the study. Any potential safety effects were noted immediately after each laser treatment and before each treatment.

The primary effectiveness endpoint of the study was met if the global percent tattoo clearance reaches at least 50% clearance (score $\geq$3) post 3, 6, or 9 treatments or at 3 months post the final treatment, as agreed by at least 2 of the 3 evaluators. Eighty-six percent (86%) of the treated tattoos achieved at least 50% clearance after 3 treatments. Therefore, the primary effectiveness endpoint was achieved. Additional efficacy analyses per investigator and subject assessments further confirm device performance.

The safety of the PicoWay System was evaluated based on the rate of occurrence and severity of adverse events reported during the study. A low rate of adverse events was reported throughout the study, with only 9 subjects with any device related adverse events of the 391 treatments performed. There were no serious adverse events in the study and no subjects discontinued from the study due to adverse events. Further, the occurrence and severity of adverse events did not increase with additional treatments performed. None or mild responses were observed for nearly all of the treatment-associated responses immediately after treatment, before treatment and during follow up. Study results also indicated a consistent trend of low levels of pain/discomfort.

Based on the clinical performance as documented in the pivotal clinical study, the PicoWay System was found to have a safety and effectiveness profile that is similar to the predicate device.

Summary of Substantial Equivalence:

The PicoWay and the predicate devices have the same intended use as laser systems used for tattoo removal with similar indications for use. The PicoWay Laser System presents similar technological characteristics as its predicate devices, including the laser type, wavelengths, device design, pulse width, frequency, spot sizes and system components. Although there are some differences between the PicoWay and its predicates in terms of the maximum pulse energy and fluence, these differences do not present any new types of safety or effectiveness questions since the PicoWay parameters are within the range reported for marketed tattoo removal laser systems. Further, PicoWay performance has been demonstrated in a clinical investigation of 60 subjects with 75 tattoos, and results confirm the safety and effectiveness profile of the device. The PicoWay device and its predicates all operate with the same mechanism of action based on selective photothermolysis of tattoo pigment particles using laser energy. Therefore, the PicoWay has the same intended use and similar indications for use, technological characteristics, and principles of operation as the predicate devices. The PicoWay is substantially equivalent to the predicate devices.

Conclusions:

Clinical testing of the PicoWay device demonstrated that the device performs as intended with a favorable safety profile. Results in the study were comparable to those reported for the predicate device, in support of substantial equivalence. The non-clinical data further support the safety of the device, and software verification and validation testing demonstrates that the PicoWay device is expected to perform as intended in the specified use conditions. The PicoWay System is substantially equivalent to the predicate devices.